

Work Site–Based Cancer Prevention: Primary Results from the Working Well Trial

ABSTRACT

Objectives. This paper presents the behavioral results of the Working Well Trial, the largest US work site cancer prevention and control trial to date.

Methods. The Working Well Trial used a randomized, matched-pair evaluation design, with the work site as the unit of assignment and analysis. The study was conducted in 111 work sites ($n = 28\,000$ workers). The effects of the intervention were evaluated by comparing changes in intervention and control work sites, as measured in cross-sectional surveys at baseline and follow-up. The 2-year intervention targeted both individuals and the work-site environment.

Results. There occurred a net reduction in the percentage of energy obtained from fat consumption of 0.37 percentage points ($P = .033$), a net increase in fiber densities of 0.13 g/1000 kcal ($P = .056$), and an average increase in fruit and vegetable intake of 0.18 servings per day ($P = .0001$). Changes in tobacco use were in the desired direction but were not significant.

Conclusions. Significant but small differences were observed for nutrition. Positive trends, but no significant results, were observed in trial-wide smoking outcomes. The observed net differences were small owing to the substantial secular changes in target behaviors. (*Am J Public Health.* 1996;86:939–947)

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Introduction

Each year approximately a half-million Americans die from cancer.¹ It is estimated that up to 70% of these cancers are associated with lifestyle or environmental exposures and are therefore preventable.² The National Cancer Institute has taken aggressive steps to implement cancer prevention and control measures to reduce cancer risk. Among its objectives are the reduction of average consumption of fat to 30% of calories or less, the increase in average consumption of fiber to 20 g to 30 g per day, the increase in servings of fruits and vegetables to five or more per day, and the reduction in the percentage of adults who smoke to 15% or less.³

Work sites have been targeted as a priority location for intervention efforts aimed at these objectives. They provide ready access to working populations, the opportunity for promoting environmental supports for behavior change, and natural structures for social support.^{4,5} Few studies, however, have employed a randomized design; often, even those with a randomized design have compared too few work sites to have adequate statistical power.⁶ Interventions have typically targeted only the individual, ignoring the organizational context. Only rarely have results been based on change in the entire work site population rather than the subset of employees participating in the program.^{7–9} The study reported here was designed to address many of these methodological problems.

The purpose of this paper is to present the primary outcomes of the Working Well Trial, the largest work-site cancer control trial in the United States.¹⁰

This study was conducted in 111 work sites by four study centers, a coordinating center, and the National Cancer Institute. The large number of work sites permitted assessment of change at the work site level. The primary hypothesis of the Working Well Trial was that a sustained 2-year comprehensive cancer control work site health promotion intervention addressing dietary change and smoking cessation, delivered by a participatory strategy that targeted individuals and the work site environment, would be more effective than a minimal intervention in achieving both individual behavioral and environmental changes. This paper reports findings on individual behavior changes.

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Methods

The Working Well Trial used a randomized, matched-pair research design, with the work site as the unit of assignment and analysis.¹⁰ Because the work site was the unit of both randomization and analysis, data from the 111 participating work sites were pooled to test the hypotheses. Cross-sectional surveys of individuals and surveys of key informants were conducted in each work site at baseline and follow-up. After baseline assessments, work sites were stratified, matched into pairs, and randomly assigned within pairs to the intervention or control group. Stratification factors were the presence of a cafeteria, work site size, type of smoking policy, company type, sex distribution, distribution of blue- and white-collar jobs, and response rate to the baseline survey.¹⁰ Evaluation of the effects of the intervention was based on the difference between intervention and control work site means within each work site pair, with adjustment for the baseline work site mean as a covariate. Calculations of sample size were based on the differences thought to be important to detect between intervention and control sites: 2 percentage points for the percentage of energy obtained from fat consumption; 3 g of fiber per day (1.5 g of fiber per 1000 kilocal); one serving of fruits and vegetables per day; and a 6-month smoking abstinence rate of 6%. The power to detect these differences was at least 80%. The sample size was determined primarily by the smoking outcomes, and excess power was therefore available for the dietary outcomes. In addition, analyses were conducted to examine work-site smoking prevalence.

Description of the Sample

The study was conducted in four study centers: the Brown University School of Medicine/Miriam Hospital, the Dana-Farber Cancer Institute/University of Massachusetts, the University of Florida, and the MD Anderson Cancer Center. The sample contained 111 work sites that employed over 28 000 workers in 16 states. (As noted in Abrams et al.,¹⁰ 114 work sites were initially recruited to this study. Because of economic dislocations, three work sites located at Brown did not participate in the final survey, leaving a total of 111 work sites. Two of these sites were from the intervention condition, one from the control. For pairwise analyses, three pairs were therefore excluded, for a total of 108 work sites.) The companies

represented manufacturing, communications, public service, and utilities. Work sites ranged in size from 49 to 1700 workers (mean = 316). As a condition of work-site participation, managers of all work sites agreed on random assignment of their work site to the intervention or control group and also agreed to administer employee and organizational surveys and to deliver the intervention based on their assignment to group. Although the work sites were a convenience sample and were recruited by the use of different strategies within each study center,¹⁰ a variety of work site environments, types of business, and geographic regions was represented. As reported previously, there were no demographic differences at baseline or follow-up between intervention and control work sites.¹¹

The Working Well Intervention

The Working Well intervention was based on a theoretical model derived from individual, organizational, and community activation theories.¹⁰ Based on these theories, the intervention focused on (1) promotion and building awareness, (2) action and skills training, and (3) maintenance of behavior and preventing relapse.^{12,13} Participatory strategies followed Rothman's community activation principles.¹⁴ This literature indicates that participation in activities is enhanced when people are involved in planning and implementation.¹⁵

A common intervention protocol specifying strategies and process objectives was implemented in the four study centers. The common intervention was targeted at eating patterns in all four study centers and smoking in three of the four study centers. Florida did not include a smoking intervention, since smoking was banned at all participating work sites, but did target cancer screening practices. The other three sites targeted smoking and nutrition plus one additional risk factor (occupational exposures to carcinogens, Dana-Farber; exercise, Brown; and smokeless tobacco, MD Anderson).

All study centers relied on an intervention model that used participatory strategies. An employee from each work site was appointed as the work-site coordinator and served as the gatekeeper to the work site. In addition, employee advisory boards were formed as a way to incorporate employee input and concerns. These boards had from 4 to 12 members, who were trained in the goals and content areas of the project.¹⁰

The protocol defined core interventions directed toward individuals; these included a kickoff event, interactive activities, posters and brochures, self-assessments, self-help materials, campaigns and contests, and direct education through classes and groups. Core interventions aimed at environmental change included consultation on the formation and implementation of smoking policy, changes in food offerings and/or nutrition education in cafeterias and vending machines, and catering policies. Additional information on the Working Well intervention is provided by Abrams et al.¹⁰

Control sites received summary results from the employee survey for distribution to employees and were asked to document health promotion activities. Three of the four study centers provided an optional minimal intervention at control sites, following a standardized protocol that included the distribution of printed materials such as posters and newsletters.

Data Collection

Data were collected from individual employees with self-administered surveys containing standard items in all study centers. Baseline data were collected from September to December 1990, and follow-up data, from September to December 1993. Eligible employees were permanent employees working at least 50% of the work time. The methods of survey distribution varied by study center.¹¹ Briefly, Florida and Brown mailed surveys to each employee in the work site, Dana-Farber mailed surveys to a random sample of employees in each work site, and MD Anderson administered questionnaires to employees at mandatory work site meetings. Follow-up reminders were sent to maximize response rates. No follow-up surveys of nonrespondents were conducted, owing to constraints imposed by the work sites.

Primary Outcomes

Nutrition outcomes. The primary evaluation of dietary change among individuals was based on assessment of nutrient intakes of fat, fiber, and fruits and vegetables, using an 88-item semi-quantitative food-frequency questionnaire with portion sizes (176 items total).^{16,17} This questionnaire was based on the Block food-frequency questionnaire, which has been validated in previous studies.¹⁸ The analysis software for the Working Well food-frequency question-

naire was based on a nutrient database developed by the University of Minnesota Nutrition Coordinating Center.¹⁹ This instrument was pretested prior to use in this study, and minor modifications were made to reflect regional dietary differences. The food-frequency questionnaire was selected for use in this study because it was able to estimate total dietary habits and was feasible for such a large-scale, population-based study.

The outcome variables calculated from the food frequency questionnaire included the percentage of energy that came from fat, grams of fiber per 1000 kilocalories, and daily servings of fruits and vegetables. The fat and fiber densities were chosen as superior to measures of total grams of fat and fiber because the densities control for total energy intake. Because grams of fiber per 1000 calories and servings of fruits and vegetables were skewed toward higher values, these variables were transformed to a logarithmic scale ($\ln(x)$ for fiber and $\ln(1 + x)$ for fruits and vegetables) in order to make the distribution of the data approximately normal. The observed means and differences as well as the covariate adjusted differences are presented here transformed back into original units. Servings of fruits and vegetables were calculated on the basis of two questions about usual intakes of fruit (excluding juice) and vegetables (excluding potatoes and salads). The number obtained was added to the responses to items about salad, potato, and fruit juice servings (weighted for serving size).¹⁸

Smoking outcomes. Analyses of two smoking outcomes were conducted with data from only the three study centers at which smoking interventions were conducted (Brown, Dana-Farber, and MD Anderson):

(1) The 6-month abstinence rate was measured by self-reported abstinence for the 6 months prior to the survey.¹⁰ The denominator included all individuals who had been employed by the work site for a minimum of 6 months and who either were current smokers or had quit smoking during the 2-year intervention period. A 6-month abstinence rate has been used by many trials as a reasonable approximation of continuous, long-term cessation.^{20,21}

(2) Work site smoking prevalence was also measured at baseline and in the final survey. Current smokers were defined as individuals who had smoked at least 100 cigarettes in their lives and currently smoked at least 1 cigarette per

day, or who defined themselves as current smokers.

Process Evaluation

A process evaluation was designed to (1) assess the extent to which the intervention was *delivered*, based on data from the "senders" of the intervention (i.e., project staff), and (2) assess the extent to which the intervention was *received*, using data from the "receivers" of the intervention (i.e., work-site employees).¹⁰ These measures were included to assess independently whether the independent variable was in fact differentially manipulated between the intervention and control conditions.

Assessment of delivery of the intervention. To ascertain the extent to which the intervention was *delivered* to the work sites randomized to the intervention condition, a process-tracking system was developed to monitor achievement of the process objectives specified in the intervention protocol.¹⁰ An a priori listing of the number and type of interventions expected at each work site yielded 15 process objectives aimed at individual change in the two risk factors plus attendance at the kickoff; additional process objectives targeted change in the worksite environment.¹⁰ A computerized relational database management system documented the types of activities implemented, the materials distributed, the time and resources expended, and other pertinent factors. To assess the delivery of intervention, the mean proportion of process objectives achieved in each work site was summed and was divided by the number of work sites.

In general, process data were recorded by research intervention staff, with the exception of MD Anderson. Because of its unique use of participatory strategies and its widely dispersed work sites, MD Anderson relied on work-site employees to function as intervention coordinators to implement and document interventions, and as a result, some intervention activities were underreported.

Assessment of receipt of the intervention. With data from the individual employee survey, two indices for each risk factor were created to calculate receipt of the intervention. The first index included items that measured awareness of intervention activities. The second index assessed activities that were directed toward behavior change. For both indices, items were scored 1 or 0; the items were added and were divided by the total number of items. Weighting was considered but was

not used, since there is no theoretical approach or literature to justify differential weighting of particular items.

Statistical Analyses

The primary analyses covered 108 work sites since the 3 work sites not completing the study represented 3 separate pairs (see "Description of the Sample" under "Methods"). Analyses conducted take into account the work site as the unit of randomization. For continuous variables (consumption of fat, fiber, and fruits and vegetables at the final employee survey), mixed linear models were used,²² where the study center and intervention condition (or treatment arm) were fixed effects, and the pair (or block) and treatment-arm-by-block interaction were random effects. The linear effect of the work site baseline mean for the variable being analyzed was included as a covariate. The effect of the intervention was evaluated by the square root of the ratio of the mean square for treatment to the mean square for treatment by block interaction and was compared to a *t* distribution. The degrees of freedom for the significance levels presented are based on the numbers of work-site pairs. Therefore, the analysis can be regarded as a weighted paired *t* test, made more efficient since the work sites vary in size. For binary response variables (6-month smoking abstinence rate and smoking prevalence at final survey), mixed model logistic regression was used,^{23,24} where the center and treatment arm were fixed effects, and the block and arm-by-block interaction were random effects. The effect of the intervention was evaluated by the ratio of the restricted maximum likelihood estimation of the regression coefficient for treatment arm to its standard error and was compared with a normal distribution.²³ Secondary analyses were done by adding age, gender, and education level into the models as covariates.

Two alternative analyses were conducted to examine the robustness of the results: (1) the generalized estimating equation,²⁵ and (2) an analysis of the mean changes within each work site pair, by means of a bootstrap *t* test.²⁶ Although data are not presented, the two analyses had results similar to those of the mixed models, with the analyses at the work-site level providing somewhat more conservative results owing to equal weighting for all work sites, which are of substantially different sizes.

Analyses were also conducted to assess differences in the intervention

TABLE 1—Nutrition Outcomes at Baseline and Follow-Up at Working Well Trial Work Sites, by Study Center

	Brown (n = 20 Work Sites)	Dana-Farber (n = 24 Work Sites)	Florida (n = 24 Work Sites)	MD Anderson (n = 40 Work Sites)	All Centers (n = 108 Work Sites)
% energy from fat					
Intervention sites					
Baseline	35.42	35.83	36.81	38.43	36.71
Follow-up	33.30	33.83	34.36	36.29	34.64
Difference (follow-up minus baseline)	-2.12	-2.00	-2.45	-2.14	-2.07
Control sites					
Baseline	35.26	35.54	36.66	39.00	36.70
Follow-up	33.67	34.17	34.71	36.90	35.00
Difference (follow-up minus baseline)	-1.59	-1.37	-1.95	-2.10	-1.70
Difference (intervention minus control)					
Baseline	0.16	0.29	0.15	-0.57	0.01
Follow-up	-0.37	-0.34	-0.35	-0.61	-0.36
Difference (follow-up minus baseline)	-0.53	-0.63	-0.50	-0.04	-0.37*
Adjusted difference ^a (SE)	-0.42 (0.27)	-0.43 (0.36)	-0.56 (0.47)	-0.09 (0.30)	-0.35* (0.16)
Dietary fiber, g/1000 kcals					
Intervention sites					
Baseline	7.92	8.02	8.72	7.83	8.03
Follow-up	8.76	8.59	9.20	8.33	8.61
Difference (follow-up minus baseline)	0.84	0.57	0.48	0.50	0.58
Control sites					
Baseline	7.89	8.06	8.35	7.80	7.96
Follow-up	8.44	8.45	8.69	8.25	8.41
Difference (follow-up minus baseline)	0.55	0.39	0.34	0.45	0.45
Difference (intervention minus control)					
Baseline	0.03	-0.04	0.37	0.03	0.07
Follow-up	0.32	0.14	0.51*	0.08	0.20*
Difference (follow-up minus baseline)	0.29	0.18	0.14*	0.05	0.13
Adjusted percent increase ^a (SE)	0.95 (2.1)	2.1 (1.2)	5.6* (2.2)	1.4 (1.5)	1.7 (0.87)
Servings of fruits and vegetables per day					
Intervention sites					
Baseline	2.69	2.71	2.66	2.40	2.60
Follow-up	2.82	2.99	2.97	2.55	2.80
Difference (follow-up minus baseline)	0.13	0.28	0.31	0.15	0.20
Control sites					
Baseline	2.66	2.74	2.60	2.37	2.58
Follow-up	2.66	2.83	2.58	2.38	2.60
Difference (follow-up minus baseline)	0.00	0.09	-0.02	0.01	0.02
Difference (intervention minus control)					
Baseline	0.03	-0.03	0.06	0.03	0.02
Follow-up	0.16	0.16*	0.39**	0.17*	0.20***
Difference (follow-up minus baseline)	0.13	0.19*	0.33**	0.14*	0.18***
Adjusted percent increase ^a (SE)	3.9 (3.7)	5.3* (1.7)	11.7** (3.5)	5.8* (2.3)	5.6*** (1.3)

Note. SE = standard error.

^aBaseline work site mean value is added as a covariate.

* $P < .05$; ** $P < .01$; *** $P < .001$.

effect for subgroups with high vs low response rates. MD Anderson's data were not used for this analysis since this study center used a different method of survey administration, which resulted in high response rates, thus confounding the response rate with the center effect. Two response-rate subgroups were created ($\leq 65\%$ and $> 65\%$). Analyses examined

the statistical significance of the effect of the interaction of treatment arm by response group. In this analysis, the blocking effect was dropped from the model, since some pairs were broken when the work sites were classified as having high or low response rates.

Analyses of the receipt of intervention examined the difference between

intervention and control work-site means within blocks. These pairwise differences were regressed against experimental design covariates employing bootstrap regression methods.²⁶ Two sets of predictor variables were employed: an intercept-only model and a model with center effects added to the regression. The intercept-only model was fit for each

TABLE 2—Observed Proportion of 6-Month Smoking Abstinence and Smoking Prevalence at Final Employee Survey, by Study Center

	Brown (n = 20 Work Sites), %	Dana-Farber (n = 24 Work Sites), %	MD Anderson (n = 40 Work Sites), %	All Centers (n = 84 Work Sites), %
6-month abstinence rate (% of quitters in total)				
Intervention sites	12.3	17.3	11.5	13.8
Control sites	11.2	12.7	12.9	12.3
Difference (intervention minus control) (95% CI)	1.04 (−2.5, 6.1)	4.61* (0.25, 9.6)	−1.49 (−4.8, 2.1)	1.53 (−1.0, 3.7)
Smoking prevalence (% of smokers in total)				
Intervention sites	24.8	20.3	19.5	21.2
Control sites	24.5	21.4	19.9	21.8
Difference (intervention minus control) (95% CI)	0.37 (−7.2, 5.5)	−1.06 (−3.8, 2.7)	−0.42 (−2.5, 1.7)	−0.66 (−3.0, 1.2)

Note. CI = confidence interval.

*Intervention minus control.

* $P < .05$.

individual study center and for all centers combined. The model with center effects added was used to examine whether the treatment effect differed among study centers.

In all analyses, two-sided tests were used and no multiple comparison adjustments were made.

Results

Response Rate Analyses

At baseline, the overall response rate to the individual survey was 69% (average work-site response rate, 72%; study center mean range, 61% to 89%). The overall response rate at the follow-up survey was 71% (average work-site response rate, 75%; study center mean range 68% to 86%). The interaction of the response-rate subgroup (cutpoint, 65%) and the intervention group indicated no relationship between the intervention effects and the work site's response rate to the individual survey (smallest $P = 0.24$).

Nutrition

For percentage of energy obtained from fat consumption, there was a net decrease of 0.37 percentage points ($P = .033$) (see Table 1). Results for each of the four study centers showed a trend in the desired direction, although only the combined results were statistically significant.

Also as shown in Table 1, the net increase in fiber consumption was only 0.13 g per 1000 kcal ($P = .056$), since control-site employees also increased fiber intake an average of 0.45 g. Results for three of the four study centers showed a trend in the desired direction, although only the results for Florida work sites (net

TABLE 3—Work Sites' Achievement of Process Objectives, by Study Center

Process Objective ^a	% Process Objectives Achieved				
	Brown	Dana-Farber	Florida	MD Anderson	All Centers Combined
Kickoff participation (50% of employees)	48	60	69	84	68
Nutrition^b					
No. work sites	11	12	12	20	55
Interactive kickoff activity (1)	100	92	100	95	96
Posters (4)	100	98	100	51	82
Video/single session presentation (3)	97	83	100	68	84
Self-assessment activity (2)	100	100	100	68	88
Self-help program (2)	100	96	96	45	78
Multisession direct education (2)	100	92	100	20	69
Campaign (1)	100	92	92	50	78
Total	100	93	98	57	82
Smoking^b					
No. work sites	11	12	NA	20	43
Interactive kickoff activity (1)	100	92	NA	45	72
Posters (4)	98	92	NA	66	81
Video/single session presentation (3)	91	56	NA	62	67
Self-assessment activity (2)	91	96	NA	75	85
Self-help program (2)	100	100	NA	60	81
Multisession direct education (2)	100	58	NA	35	58
Campaign (1)	100	83	NA	50	72
Total	97	82	NA	56	74

Note. NA = not applicable.

^aExcludes process objectives directed toward environmental change; numbers in parentheses indicate the number of times an activity was to be done.

^bConducted in each intervention work site.

increase of 0.14, $P = 0.024$) were statistically significant. The intake of fruits and vegetables increased a net average of 0.18 servings per day for all study centers ($P = .0001$). Increased fruit and vegetable consumption was consistently higher in

intervention sites and was negligible in most control sites.

Smoking

For the trial overall, there was a nonsignificant difference of 1.53% in the

TABLE 4—Bootstrap Regression Estimates for Awareness and Action Indexes, by Study Center

Awareness/ Action Index	Intervention–Control Difference	SE	P	95% CI
Smoking awareness				
Brown	0.15	0.09	0.15	–0.05, 0.36
Dana-Farber	0.09	0.06	0.15	–0.02, 0.28
MD Anderson	0.16	0.04	0.00	0.08, 0.27
All centers combined	0.14	0.03	0.00	0.08, 0.22
Nutrition awareness				
Brown	0.22	0.07	0.02	0.05, 0.40
Dana-Farber	0.22	0.05	0.00	0.10, 0.33
Florida	0.14	0.03	0.01	0.09, 0.24
MD Anderson	0.15	0.04	0.00	0.07, 0.24
All centers combined	0.17	0.02	0.00	0.13, 0.22
Smoking action				
Brown	0.18	0.04	0.01	0.11, 0.30
Dana-Farber	0.12	0.01	0.00	0.10, 0.17
MD Anderson	0.18	0.03	0.00	0.13, 0.24
All centers combined	0.13	0.02	0.00	0.10, 0.17
Nutrition action				
Brown	0.31	0.03	0.00	0.25, 0.40
Dana-Farber	0.24	0.03	0.00	0.18, 0.29
Florida	0.32	0.02	0.00	0.26, 0.37
MD Anderson	0.20	0.04	0.00	0.13, 0.29
All centers combined	0.26	0.02	0.01	0.22, 0.29

Note. SE = standard error; CI = confidence interval.

6-month quit rates between intervention and control work sites (see Table 2).

We also examined changes in smoking prevalence, although sufficient power for this outcome was not part of the design of the Working Well Trial. As shown in Table 2, smoking prevalence dropped considerably in both the intervention (from 24.5% to 21.2%) and control (from 25.8% to 21.8%) conditions in the 2 years of the trial.

Delivery of the Intervention

The duration of the intervention varied, with the median (and range) number of weeks between the kickoff event and the final survey at the four study centers as follows: at Brown, 120 (117 to 125); at Dana-Farber, 97 (82 to 120); at Florida, 121 (102 to 123); and at MD Anderson, 97 (80 to 104).

Table 3 shows the percentage of the process objectives achieved by study center and for all study centers combined. The process objective that required that 50% of employees attend the overall kickoff event was met by all study centers except Brown, where average work-site kickoff participation was 48%. Overall participation in the kickoff averaged 68%.

For nutrition, there was high delivery of the intervention in three of the four

centers. For the trial overall, process objective attainment in this risk factor was high, with an overall 82% of process objectives attained. Process objectives attained for smoking-control activities were not as high as for nutrition, with an overall trial attainment of 74%.

Receipt of Intervention

Cronbach's alpha was computed for each receipt index, and values were found to be uniformly high (range = .78 to .85). Table 4 shows the treatment effects on the receipt of the intervention activities by study center and for the trial overall. The center-by-treatment-condition interaction was tested for each index, and no significant interactions were observed. For each of the receipt indices, an intervention-minus-control difference was significant ($P < .001$). The data provide evidence that intervention materials and activities reached employees in the work sites; furthermore, these materials and activities were utilized to a greater extent than any programs or materials available in control work sites.

Discussion

The Working Well Trial measured changes in eating patterns and smoking

behavior after a sustained 2-year intervention. A common intervention protocol was applied to the four study centers, covering 111 work sites that were randomly assigned to intervention or control conditions. The study had sufficient power for study center-specific evaluations as well as for data from all sites combined. Results presented here focused on the combined data reflecting individual behavior changes. The work site was the unit of randomization, intervention, and analysis. Analyses were also conducted to eliminate the possibility of response-rate bias.

For the trial as a whole, significant results were observed for two of three individual nutrition outcomes. Although the percentage of energy obtained from fat consumption decreased by 2.07 percentage points between baseline and follow-up, the percentage of energy from fat decreased 1.70 percentage points among employees in the control sites. The level of change observed in control sites suggests a modest secular trend in the reduction of fat consumption. The largest net effect for nutrition was change in the consumption of fruits and vegetables. Intake of fruits and vegetables increased an average of 0.18 servings for all study centers; one study center obtained a difference of approximately a third of a serving.

The increased intake of fruits and vegetables may be interpreted, for example, as a change in one fifth of a serving for every individual or as one person in five having increased consumption by a full serving. Results reported here represent changes occurring in the entire work-site population, among employees in intervention sites who actively participated in the intervention as well as those who were unaware of the program. Additional analyses are needed to assess whether small changes were made by a majority of respondents or whether there were larger changes concentrated among fewer individuals. Although such changes are small in clinical terms, they may be indicative of a potentially important public health impact if they are maintained and are cumulative, when we consider the large numbers of workers represented by this trial.

The intervention failed to produce statistically significant differences between intervention and control sites for measures of smoking. Only at one study center, Dana-Farber, was the difference in 6-month quit rates statistically significant. This significant finding in one site suggests that effective work-site smoking

cessation interventions may be possible; there still remains the important challenge of determining how best to intervene in work sites to promote smoking cessation. Additional analyses will examine the role of work site characteristics in the observed changes.

The changes in smoking behavior observed in these intervention work sites compare favorably with abstinence rates reported in previous minimal intervention trials¹⁹ and with reductions in smoking prevalence reported by similar work site-based interventions.²⁷ However, the control group's 6-month smoking abstinence rate (11.2%) is somewhat higher than expected, based on several comparable prior reports. For example, a recent examination of 10 prospective studies of self-quitters found a median 6-month abstinence rate of 6.0%.²¹ Similarly, the 1987 National Health Interview Survey found that only 6.0% of ever-smokers who attempted to quit in the past 12 months were continuously abstinent for more than 3 months.²⁸ At the Working Well baseline, the 4- to 12-month continuous abstinence rate was 6.0%.¹¹ This increase in quit rates within the control group may reflect the high level of smoking-related intervention activities at control sites, as indicated by the data on the receipt of the intervention. Some control sites also received minimal interventions such as the distribution of posters and brochures. In particular, smoking policy awareness and implementation at all work sites was high; contributing to this trend may have been the release, midway through the trial, of the Environmental Protection Agency report on environmental tobacco smoke as a carcinogen.²⁹

More powerful intervention strategies may be needed to increase smoking cessation rates beyond the current secular trend noted in the Working Well Trial control work sites. This trial used a state-of-the-art intervention model based on participatory public health strategies.³⁰ Some possible ways of increasing the potency of the intervention are to provide programming of increased intensity and duration, to integrate the health promotion intervention with an intervention targeting occupational health and safety or other health-related concerns of workers, to incorporate the use of pharmacological aids, and to target specific types of work sites or workers, such as disadvantaged or young smokers.

Consistently, the intervention receipt indices, which compared employee reports of the level of intervention activities,

were significantly higher in the intervention sites than in control sites. Respondents were more likely to report awareness of nutrition- than smoking-related intervention activities, perhaps because nutrition is important to more people than is smoking. Similarly, a greater percentage of nutrition- than smoking-related process objectives were achieved; this probably contributed to the observed differences in significant outcomes for nutrition. The analyses of the receipt of intervention indices also underline the high level of intervention activity in control work sites, reflecting the secular trend toward increasing health promotion efforts at the work site.

The intervention protocol also aimed to promote the adoption of work-site smoking bans and increase the availability of healthy foods at the work place since behavior change and its maintenance requires a supportive social environment.³¹⁻³³ It was beyond the scope of this paper to present changes in the work site environment resulting from this intervention.

Several limitations must be noted in the interpretation of these results. For both nutrition and smoking outcomes, self-reports were used to assess change in the outcome variables. For nutrition, the food-frequency questionnaire was previously validated.³⁴⁻³⁹ However, the need for biochemical validation of smoking cessation in field studies such as this has been increasingly challenged.^{28,40}

Work sites were not randomly selected for inclusion in this study; although a wide range of company types and geographic regions were included, these results should be generalized only to similar work sites. Baseline results suggested that both intervention and control work sites were more likely to have had health promotion activities than worksites nationwide,¹¹ a selection bias that may have contributed to the high level of behavior change in the control work sites. By necessity, only work sites where there is interest in health promotion are likely to be enrolled in studies such as these.

Centers and work sites differed in a number of dimensions, which certainly influenced uniform application of the intervention. Although a common intervention protocol was used, there were variations in the combination of risk factors addressed and in the intensity of the contacts with the work sites (e.g., work sites at MD Anderson were scattered across 11 states and therefore had less intensive contact with project staff). The

impact of variations in levels of delivered and received interventions, policy changes, and participatory strategies on the observed outcomes will be explored in future papers. The interaction of multiple risk factor interventions, as implemented and sequenced at various work sites, may have contributed to center differences in observed outcomes.

Finally, the 2-year duration of the Working Well Trial intervention may not have been long enough to observe the intended effects, owing to several features of the intervention design. First, the Working Well Trial intervention used the stage-of-change model to develop an intervention that emphasized awareness, active change, and maintenance activities at the work site, with the understanding that change occurs in small increments in a cyclical pattern over time.⁴¹ A longer intervention period may be needed to observe the movement of individuals through the varying stages of readiness for change. Second, following a participatory strategies model, employee advisory boards were formed to provide worker input into intervention planning and implementation. Organization and maintenance of these boards required substantial investments of time and in some cases may have delayed the start-up of intervention delivery.

In conclusion, the Working Well Trial work-site intervention resulted in small but significant decreases in fat consumption and increases in fruit and vegetable intake. The potential public health significance of such small changes must be debated within the context of the work site-wide nature of this intervention and its evaluation. Although significant smoking cessation differences were not observed trial-wide, the success of one study center in achieving a significant difference in cessation suggests the opportunity for future initiatives if the components and attributes of successful cessation interventions can be identified. For both the nutrition and smoking outcomes, sizable secular trends observed during the study period may have accounted for some of the reduced magnitude of the observed differences between intervention and control groups. Process-tracking data supported the overall integrity of the delivery of the intervention, and worker data showed significantly greater awareness of and participation in nutrition and smoking-control activities in intervention sites. If more substantial changes are to be expected throughout the entire work-site population, future work-site interventions

may need to reexamine the intensity and duration of interventions, the sequencing and timing of environmental interventions, and the potential synergism of multiple risk factor interventions. □

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